

**UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:22-md-03036- RJC**

**IN RE: GARDASIL PRODUCTS
LIABILITY LITIGATION**

MDL No. 3036

**THIS DOCUMENT RELATES
TO ALL CASES**

DEFENDANT FACT SHEETS ORDER

I. SCOPE OF ORDER

This Defendant Fact Sheets Order (“DFSO”) governs the form and schedule for service of Defendant Fact Sheets (“DFS”) by Merck & Co., Inc. and Merck Sharp & Dohme LLC (collectively, “DEFENDANTS”) in all cases that were (1) transferred to this Court by the Judicial Panel on Multidistrict Litigation (“JPML”) pursuant to its August 4, 2022 Order; (2) subsequently transferred to MDL 3036 by the JPML pursuant to Rule 7.4 of the Rules of Procedure of that Panel; or (3) originally filed in, transferred to, removed to, or reassigned to MDL 3036. Collectively, these cases shall be referred to as “Subject Actions.”

II. DEFENDANT FACT SHEETS

A. Instructions for Completion and Service of DFS and Production of Responsive Documents

The form of DFS that shall be used in MDL 3036 for all Subject Actions is attached as **Exhibit A**. In accordance with the schedule and provisions set forth in Section II.B. below, DEFENDANTS shall, for each Subject Action in which a Plaintiff serves DEFENDANTS with a substantially complete Plaintiff Fact Sheet (“PFS”) Part I and Part II, complete and

execute a DFS and produce to Plaintiff in the Subject Action all records required under the DFS. Part I and Part II of the PFS must include the Plaintiff's name(s) or address(es), the Plaintiff's HEALTH CARE PROVIDER's name(s), the Plaintiff's HEALTH CARE PROVIDER(s) address(es) and the GARDASIL/GARDASIL 9 lot number(s). DEFENDANTS will be unable to provide responses to certain sections of the DFS if this information is not provided in the PFS. The questions and requests for production contained in the DFS are non-objectionable and shall be answered fully unless information is privileged or protected by the attorney-client privilege.

DEFENDANTS' responses to the DFS shall be treated as answers to interrogatories under Federal Rule of Civil Procedure 33 and responses to requests for production of documents under Federal Rule of Civil Procedure 34 and shall be supplemented in accordance with Federal Rule of Civil Procedure 26. The completed DFS will be governed by the standards applicable to written discovery under Federal Rules of Civil Procedure 26 through 37. The above does not prohibit DEFENDANTS from withholding or redacting information on the basis of a recognized privilege. To the extent DEFENDANTS withhold any information on the ground of privilege, DEFENDANTS shall identify the privilege being asserted in a privilege log to be produced pursuant to the Privilege Log Protocol to be negotiated and entered in MDL 3036. Post-complaint materials need not be logged. Furthermore, the production of responsive documents should comply with the requirements of the Pretrial Order regarding Electronically Stored Information (Doc. No. 96). The DFS and responsive documents will be subject to the Stipulated Protective Order (Doc. No.70) entered in this matter.

Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions or the

admissibility of evidence at trial. Each completed DFS shall be verified, signed and dated by someone authorized to sign on behalf of the DEFENDANTS as if it were interrogatory responses under Federal Rule Civil Procedure 33.

B. Timing and Service of DFS

1. Deadline for Serving a DFS

In all Subject Actions, DEFENDANTS shall complete and serve a DFS for each Plaintiff no later than forty-five (45) days from the date on which each Plaintiff serves his or her substantially complete Plaintiff Fact Sheet (“PFS”) Part II or an amended PFS Part II pursuant to Plaintiff Fact Sheets Order (“PFSO”) (Doc. No. 78). An alleged deficiency in the PFS will not delay service of the DFS; however, Part I and Part II of the PFS must include the Plaintiff’s name(s) or address(es), the Plaintiff’s HEALTH CARE PROVIDER’s name(s), the Plaintiff’s HEALTH CARE PROVIDER(s) address(es) and the GARDASIL/GARDASIL 9 lot number(s). DEFENDANTS will be unable to provide responses to certain sections of the DFS if this information is not provided in the PFS.

If a Plaintiff has received (1) an “Alert of Non-Compliance with PFS – Part I Requirements”; or (2) an “Alert of Non-Compliance with PFS – Part II Requirements” due to a Plaintiff’s failure to serve a PFS Part I or Part II, then DEFENDANTS obligation to complete and serve a DFS for that Plaintiff does not begin to run until: (1) Plaintiff provides a substantially complete PFS Part I and II; (2) DEFENDANTS’ Motion to Compel a complete PFS Part I or Part II has been resolved by the Court; or (3) by agreement of the Parties.

Notwithstanding Section B.1., above, the Parties will separately negotiate, at a

later date, any additional requests in each of the Actions later selected as a Bellwether case in this MDL.

2. Service of the DFS

All completed DFS and responsive records and materials will be (a) served directly on the individual Plaintiff's counsel of record who served the PFS triggering the DFS obligation, using the email address(es) identified on the individual case docket in the U.S. District Court for the Western District of North Carolina's ECF system and (b) a courtesy copy shall be produced to the designee of the Plaintiffs' Steering Committee at GardasilDFS@LanierLawFirm.com.

C. Claims by Plaintiff That a DFS Is Not Substantially Complete and/or Contains Material Deficiencies and/or DEFENDANTS' Failure to Submit a DFS.

1. Not Substantially Complete and/or Contains Material Deficiencies

In the event that a Plaintiff contends that a DFS, and responsive documents produced pursuant to the DFS, is not substantially complete and/or contains material deficiencies, the individual Plaintiff's counsel of record shall notify DEFENDANTS' counsel of the purported deficiency(ies) by email at GardasilDefenseFactSheets@morganlewis.com within thirty (30) days of receipt of the DFS, which shall identify with specificity the purported deficiencies. Plaintiff's email communication shall identify the case name, docket number, deadline date, and shall state the basis for Plaintiff's contention that the DFS contains material deficiencies and/or is not substantially complete.

DEFENDANTS will have thirty (30) days from receipt of a deficiency letter to cure the alleged deficiencies noted in the DFS and telephonically or virtually meet

and confer with Plaintiff's counsel, if DEFENDANTS choose to do so. Failure of DEFENDANTS' counsel to meet and confer does not delay DEFENDANTS' ability to file motions under this section. A courtesy copy of any email notifying DEFENDANTS of deficiencies shall be produced to the designee of the Plaintiffs' Steering Committee at GardasilDFS@LanierLawFirm.com.

In the event that the purported deficiencies have not been cured in this thirty (30) day period, Plaintiff, through their individually retained counsel, may request to meet and confer with DEFENDANTS regarding the alleged deficiency(ies). Plaintiff's counsel shall notify DEFENDANTS in writing via email of the request to meet and confer and state that the meet and confer shall occur within fourteen (14) days. The Parties' meet and confer period shall begin upon receipt of the email by DEFENDANTS and, absent agreement of the Parties, shall be completed by the conclusion of the fourteen (14) days.

Following the meet and confer period, should DEFENDANTS (i) fail to cure the alleged deficiency(ies); (ii) fail to assert objections with respect to the requests/questions that are the subject of the claimed deficiencies; (iii) fail to respond to or participate in the meet and confer process; or (iv) otherwise fail to provide responses, and absent agreement of the Parties to further extend the meet and confer period, at any time following expiration of the fourteen (14) day meet and confer, the individual Plaintiffs' counsel may file a motion to compel with respect to the allegedly deficient information.

The filing of a motion to compel made pursuant to this Order shall be via ECF. A courtesy copy of any motion to compel shall be produced to the designee of the

Plaintiffs' Steering Committee at GardasilDFS@LanierLawFirm.com.

DEFENDANTS' response to a motion to compel made pursuant to this provision shall be filed and served within fourteen (14) days following the date of service of the motion. The Plaintiff's reply, if any, to DEFENDANTS' response shall be filed within seven (7) days following the date of service of DEFENDANTS' response in opposition to the motion.

2. Failure to Serve a DFS

Should DEFENDANTS fail to serve an executed DFS within the time required in this Order, the individual Plaintiff's counsel shall send a Notice of Non-Compliance letter via e-mail to DEFENDANTS at GardasilDefenseFactSheets@morganlewis.com. A courtesy copy shall be produced to the designee of the Plaintiffs' Steering Committee at GardasilDFS@LanierLawFirm.com. Following receipt of the Notice of Non-Compliance letter, DEFENDANTS shall have twenty-one (21) days to serve the DFS.

At any time following the expiration of the twenty-one (21) day period after DEFENDANTS receive a Notice of Non-Compliance, absent agreement of the Parties to further extend the period for meeting and conferring, a Plaintiff may move the Court for an order compelling service of a complete DFS.

Any such filing shall be via ECF. A courtesy copy of the motion to compel shall be produced to the designee of the Plaintiffs' Steering Committee at GardasilDFS@LanierLawFirm.com. DEFENDANTS' response to a motion to compel made pursuant to this provision shall be filed and served within fourteen (14) days following the date of service of the motion. The Plaintiff's reply, if any, to DEFENDANTS' response shall be filed within seven (7) days following the date of

service of DEFENDANTS' response in opposition to the motion.

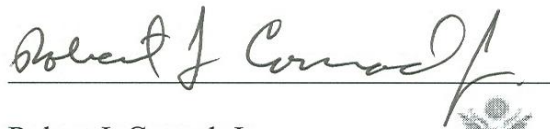
The obligation to take any action authorized in this Order related to deficiencies in a DFS or failure to serve a DFS shall be the sole obligation of the individual attorney hired by the individual Plaintiff. Plaintiffs' Co-Lead Counsel, Liaison Counsel, Plaintiffs' Executive Committee, and Plaintiffs' Steering Committee shall have no obligation to take any action with regard to the DFS process for any individual Plaintiff.

D. Documents Obtained Designated as Confidential.

Any records served by DEFENDANTS pursuant to this DFSO shall be deemed confidential under the terms of the Stipulated Protective Order (Doc. No. 70) entered in this MDL.

SO ORDERED.

Signed: June 26, 2023

A handwritten signature in black ink, reading "Robert J. Conrad, Jr.", written over a horizontal line.

Robert J. Conrad, Jr.
United States District Judge



EXHIBIT A – DEFENDANT FACT SHEETS ORDER

**UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:22-md-03036-RJC**

**IN RE: GARDASIL PRODUCTS LIABILITY
LITIGATION**

MDL No. 3036

**DEFENDANT FACT SHEET FOR
DEFENDANTS MERCK & CO., INC. AND MERCK SHARP & DOHME LLC**

This Defendant Fact Sheet (“DFS”) pertains to Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC (collectively “DEFENDANTS”) only.

For each case, DEFENDANTS must complete and serve this DFS pursuant to the terms in the Defendant Fact Sheets Order (“DFS”) regarding DFSs. DEFENDANTS shall provide the answers and responses herein and produce responsive DOCUMENTS pursuant to the Stipulated Protective Order (Doc. No. 70). Information provided will only be used for purposes related to this litigation and may be disclosed only as permitted by the Protective Order in this litigation. This DFS is completed pursuant to the Federal Rules of Civil Procedure governing discovery.

DEFENDANTS’ answers and responses herein are based on available responsive information that can be reasonably searched and obtained from DEFENDANTS’ readily accessible electronic database(s) maintained in the ordinary course of business. DEFENDANTS do not have an obligation to review or produce information for this DFS from any other source, including, but not limited to, department or custodial files. The Parties will separately negotiate potential custodial file collections and productions in the 16 cases selected for inclusion in the Initial Bellwether Pool as defined by the First Case Management Order separate and apart from the DFS. DEFENDANTS reserve the right to supplement these answers and responses in accordance with the Federal Rules of Civil Procedure and DFSO regarding DFSs.

INSTRUCTIONS

In completing this DFS, each response must provide the substantive information, documents, and data responsive to the questions set forth below for each Plaintiff. No question shall be left unanswered or blank unless the information is protected by the attorney-client privilege, the work-product doctrine, or any other privilege recognized by the Federal Rules of Evidence and Federal Rules of Civil Procedure. If information is withheld as privileged, a privilege log will be provided pursuant to the Privilege Log Protocol to be negotiated and entered in MDL 3036. The parties agree that post-complaint materials need not be logged. In the event this DFS does not provide enough space to complete the responses or answers, please attach additional sheets if necessary.

In providing answers and responses in this DFS, DEFENDANTS do not have an obligation to review medical records or any other source of information to identify Plaintiff’s name(s), Plaintiff’s

addresses(es), Plaintiff's HEALTH CARE PROVIDER'S name(s), Plaintiff's HEALTH CARE PROVIDER'S address(es) or the GARDASIL/GARDASIL 9 lot number(s) that Plaintiff received but rather, DEFENDANTS' answers and responses will be based off information provided in Parts I and II of the Plaintiff Fact Sheet ("PFS") pursuant to DFSO. If Parts I and II of a PFS do not identify all variations of a Plaintiff's name(s) or address(es), the Plaintiff's HEALTH CARE PROVIDER's name(s), the Plaintiff's HEALTH CARE PROVIDER(s) address(es) or the GARDASIL/GARDASIL 9 lot number(s), DEFENDANTS will be unable to provide responses to certain sections of the DFS and will respond as such. This does not constitute a DFS deficiency. If a PFS is missing such information that renders DEFENDANTS unable to provide responses to certain sections of the DFS, Plaintiffs reserve the right to supplement the PFS with said information, or otherwise provide updated information to DEFENDANTS via letter response by Plaintiff's counsel that includes a verification of the amended responses signed by the Plaintiff to DEFENDANTS' counsel. Upon receipt of an updated PFS and notice that a Plaintiff is requesting an updated DFS for that case, DEFENDANTS will have 30 days to produce additional responsive information.

When producing DOCUMENTS that are responsive to a request in this DFS, DEFENDANTS will only produce DOCUMENTS that are in their possession, custody, or control. The produced DOCUMENTS shall be identified by Bates number and will be listed under the applicable DFS request(s). If the response to any request herein is "no data found," that response should be entered in the appropriate location(s). If "no data found" is provided in response to a given section, this means that DEFENDANTS have conducted a diligent, good faith search for the requested data, but the search has yielded no data. Such a finding does not preclude later discovery into DEFENDANTS' other sources of information or data.

Data output produced in response to the DFS may be responsive to more than one question contained in the DFS. DEFENDANTS will identify each request in this DFS to which this data is responsive and list the applicable Bates number(s). Data produced by DEFENDANTS in response to a request will be deemed a complete response to that question based upon information in their possession at the time of the service of this DFS.

Certain output from databases cannot be provided on a single page and cannot be manipulated and, in such a situation, the data will be divided into multiple pages for production purposes. Nevertheless, DEFENDANTS will strive in good faith to produce the data in a manner that makes it easy to review and analyze.

In searching for and producing data responsive to this DFS, a database may return data that is non-responsive or otherwise irrelevant to PLAINTIFF and/or a HEALTH CARE PROVIDER. An example of such data is privacy information (e.g., social security numbers). If such data is redacted in the DFS package, the DFS shall not be deemed deficient in this regard.

DEFINITIONS

As used herein, the below-listed terms are defined as follows:

"YOU," "YOUR," "YOURS" or "DEFENDANTS" means Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC, and the answers and responses to this DFS are by and for those two entities only.

"GARDASIL" refers to the Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant manufactured and marketed by Merck.

“GARDASIL 9” refers to the Human Papillomavirus 9-valent (Types 6, 11, 16, 18, 31, 33, 45, 52, and 58) Vaccine, Recombinant manufactured and marketed by Merck.

“HEALTH CARE PROVIDER” means any physician, nurse or nurse practitioner or any other persons who recommended, administered, provided information concerning and/or discussed GARDASIL/GARDASIL 9 with PLAINTIFF as identified by name and address in Sections I.B.1 and I.C.1-2 of the PFS, Part II in the case.

“DOCUMENTS” shall, consistent with Federal Rule of Civil Procedure 34(a)(1)(A), refer to any “designated documents or electronically stored information – including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium form which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.”

“PLAINTIFF” means the individual who was vaccinated with GARDASIL or GARDASIL 9 and who is alleging personal injury as a result of receiving GARDASIL or GARDASIL 9 vaccination in this case and whose name is listed below in Section I.

“RELEVANT TIME PERIOD” means, unless otherwise identified in a particular request, the time period from 2006 to the Present (meaning the date the DFS collection requests are submitted to DEFENDANTS).

I. CASE INFORMATION

This Defendant Fact Sheet pertains to the following case:

Case Caption: _____ *v. Merck & Co., Inc., et al.*

Civil Action No.: _____

Plaintiff Name: _____

Date this DFS was completed: _____

Date this DFS was supplemented, if applicable _____

II. CONTACTS WITH PLAINTIFF’S HEALTH CARE PROVIDER(S)

In Sections I.B.1 and I.C.1-2 of the PFS, Part II in this case, PLAINTIFF is to identify the HEALTH CARE PROVIDER(S) (by name(s) and address(es)) who recommended, administered, provided information concerning, and/or discussed GARDASIL/GARDASIL 9 with PLAINTIFF (hereinafter “HEALTH CARE PROVIDER”) For each HEALTH CARE PROVIDER identified in Sections I.B.1 and I.C.1-2 by name and address, please provide FOR THE RELEVANT TIME PERIOD the following:

- A. Identify contacts between YOUR professional representative(s) and the HEALTH CARE PROVIDER(s) regarding GARDASIL/GARDASIL 9 identified in Sections I.B.1 and I.C.1-2 of the PFS, Part II for the RELEVANT TIME PERIOD. YOUR response should include: each

Professional Representative's name, the HEALTH CARE PROVIDER's name, the dates of contact, and the available call/detail notes for the identified contacts.

- B. For each professional representative, provide the name(s) of the professional representative(s) supervisor/district manager(s).
- C. If the professional representative(s) identified in response to questions II.A-B is no longer an employee of DEFENDANTS, provide his/her last known address, if known.
- D. Produce a copy of any Medical Information Request ("MIR") or Professional Information Request ("PIR") related to GARDASIL/GARDASIL 9 that YOU sent in the RELEVANT TIME PERIOD to the HEALTH CARE PROVIDER(s) identified by name and address in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2.
- E. If the HEALTH CARE PROVIDER(S) identified in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2 of the PFS, Part II contacted YOU in the RELEVANT TIME PERIOD by any other means not already addressed in this Section concerning and/or requesting information regarding GARDASIL/GARDASIL 9, its indications, potential side effects and/or other risks, or to report adverse events, produce DOCUMENTS reflecting these contacts, including YOUR response(s), if any.

III. CONSULTING WITH PLAINTIFF'S HEALTH CARE PROVIDER(S)

- A. For each HEALTH CARE PROVIDER identified by name and address in Sections I.B.1 and I.C.1-2 of the PFS, Part II, disclose whether he/she was ever retained by YOU or compensated by YOU to be a clinical investigator, consultant, advisory board member and/or a member of YOUR speaking program, if that retention related to GARDASIL/GARDASIL 9, if available.
- B. For each HEALTH CARE PROVIDER identified in Section III.A. above, provide the date of any compensation, the amount of any compensation, the payee of any compensation, the nature of the work performed for each compensation, if available, and if it pertains to GARDASIL/GARDASIL 9.
- C. Please identify and produce any and all consulting agreements/contracts and/or retainer agreements/contracts entered into by YOU with the HEALTH CARE PROVIDER identified in Sections III.A, if available and if it pertains to GARDASIL/GARDASIL 9.

IV. KEY OPINION LEADER INFORMATION

For each HEALTH CARE PROVIDER identified by name and address in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2, disclose whether he/she was identified by YOU as a "Key Opinion Leader" related to GARDASIL/GARDASIL 9 within the RELEVANT TIME PERIOD.

V. SALE TO HEALTH CARE PROVIDER(S) DIRECTLY

- A. Did YOU sell, distribute, deliver, or otherwise provide

GARDASIL/GARDASIL 9 to PLAINTIFF's HEALTH CARE PROVIDER(S) as identified by name and address in Sections I.B.1 and I.C.1-2 of the PFS, Part II during the time period of three years preceding Plaintiff's first administration of GARDASIL/GARDASIL 9 through the Plaintiff's last administration of GARDASIL/GARDASIL 9?

____ Yes ____ No

- B. If YOUR answer is "Yes" to Question A. above, please provide a list of all deliveries or shipments of GARDASIL/GARDASIL 9 sold, distributed, or otherwise provided to each of PLAINTIFF'S HEALTH CARE PROVIDER as identified in the PFS for the time period spanning from three years prior to Plaintiff's first administration of GARDASIL/GARDASIL 9 through Plaintiff's last administration of GARDASIL/GARDASIL 9. Please include the the date of shipment/distribution of GARDASIL/GARDASIL 9, the amount of GARDASIL/GARDASIL 9 distributed on said date, and the identification number for the batch shipped if available.

VI. GARDASIL/GARDASIL 9 CERTIFICATE(S) OF ANALYSIS(ES) AND FDA RELEASE RECORD(S)

- A. Produce a copy of the Certificate of Analysis(es) for the Gardasil/Gardasil 9 batch(es) for the Lot Number(s) identified in Section I.B.1 in the Plaintiff's PFS Part II.
- B. Produce a copy of the FDA Release letter(s) for the Lot Number(s) identified in Section I.B.1 in the Plaintiff's PFS Part II.

VII. ADDITIONAL INFORMATION WITHIN THE RELEVANT TIME PERIOD

- A. For each HEALTH CARE PROVIDER identified in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2 of the PFS, produce IMS data tracking that individual's prescribing practices with respect to GARDASIL/GARDASIL 9.
- B. For each HEALTH CARE PROVIDER identified in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2 of the PFS, identify and produce information of conferences, lectures, luncheons, dinners or other similar meetings or events sponsored or co-sponsored by DEFENDANTS related to GARDASIL/GARDASIL 9, HPV, Cervical Cancer or Vaccines that he/she attended, if available.
- C. Did YOU submit information and/or file DOCUMENTS relating to PLAINTIFF with the Vaccine Adverse Event Reporting System ("VAERS")?

☐ Yes ☐ No

- D. To the extent YOU have not already done so, please provide copies of the VAERS form(s) submitted to FDA relating to PLAINTIFF that pre-date the filing of PLAINTIFF's Complaint.
- E. Please identify and produce information reflecting GARDASIL/GARDASIL 9-related communications, if any, between YOU and PLAINTIFF or any person acting on behalf of Plaintiff, if such communications are identified by DEFENDANTS search of the centralized databases. DEFENDANTS search(es) will be limited to Plaintiff's name(s) and address(es), Plaintiff's HEALTHCARE PROVIDER'S name(s) and address(es) and Plaintiff's GARDASIL/GARDASIL 9 lot number(s) as provided in the PFS.
- F. Please identify and produce information reflecting GARDASIL/GARDASIL 9-related Dear Doctor Letter(s), if any, that DEFENDANTS sent to any HEALTH CARE PROVIDER identified in PLAINTIFF's PFS Sections I.B.1 and I.C.1-2 of the PFS prior to the filing of PLAINTIFF's Complaint.

CERTIFICATION

I am employed by _____, one of the DEFENDANTS in this litigation. I am authorized by _____ [name of other DEFENDANTS] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for DEFENDANTS, upon whose advice and information I relied. I declare under penalty of perjury subject to 28 U.S.C. § 1746 that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Signature

Print Name

Date